

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 8 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**REPLY IN FURTHER SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND
TESTIMONY OF VLADIMIR IAKOVLEV, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) submit this reply in further support of their motion to exclude the opinions and testimony of Vladimir Iakovlev, M.D. For the reasons stated below and as stated in Ethicon’s Daubert briefing, Dr. Iakovlev’s opinions should be excluded.

I. Adoption of Prior Reply Regarding Dr. Iakovlev’s General Opinions

Ethicon hereby adopts and incorporates by reference the Daubert reply filed in relation to Vladimir Iakovlev, M.D. for Ethicon Wave 4, Dkt. #3865. Ethicon respectfully asks this Court to exclude Dr. Iakovlev’s testimony, for the reasons expressed in the Wave 4 briefing.

II. The Court should exclude Dr. Iakovlev’s opinions regarding Mersilene mesh.¹

Dr. Iakovlev has focused his prior work and research regarding mesh on monofilament polypropylene mesh. *See* Iakovlev 9/11/18 Dep. Tr. 8:20-9:14, 9:21-24, 10:21-11:2, 12:2-6. He has not focused on multifilament mesh. *Id.* at 10:17-18. His publications do not deal with Mersilene mesh. *Id.* at 11:21-12:1. Despite this, Dr. Iakovlev now seeks to offer general

¹ This portion of the Reply applies only to the Cheryl Berden case (Cheryl Berden, et al. v. Ethicon, Inc., et al., Case No. 2:14-cv-21966), as it is the only Wave 8 case in which Dr. Iakovlev has provided his general opinions regarding Mersilene mesh.

opinions regarding the risks of erosion and infection associated with Mersilene mesh. Because Dr. Iakovlev's opinions do not contain sufficient bases and are unreliable, they should be excluded.

Because he has no pertinent experience with Mersilene, Dr. Iakovlev attempts to use general concepts about infection and mesh erosion to argue that Mersilene mesh has rates of these complications higher than other meshes. Dr. Iakovlev's opinions lack the requisite reliable scientific bases to opine that Mersilene is associated with higher complication rates than other meshes. Where Dr. Iakovlev does not have support for increased erosion and infection rates with Mersilene, he and the Plaintiff point to multifilament mesh versus monofilament mesh, using the Amid classification system. Instead of limiting his opinion to "Amid Type III mesh (i.e., multifilament mesh) carries higher risks than Amid Type I (i.e., monofilament mesh)," as a reading of Plaintiff's response would suggest, Dr. Iakovlev goes further and opines that, because Mersilene mesh is Type III, it has a higher rate of infection and erosion than other meshes. He offers these opinions despite the fact that he did not identify an overall rate of either complication with Mersilene. Dr. Iakovlev's opinion is unreliable because he has not undertaken a sufficient analysis or based his opinions on sufficient data or experience. One must know the rate before opining it is higher than another rate. Because Dr. Iakovlev does not, he cannot offer these opinions.

The Plaintiff contends that Ethicon in its motion misrepresented Dr. Iakovlev's testimony regarding his prior experience with Mersilene mesh. *See* Pl. Resp. at 2-3. Despite Plaintiff's contention, Dr. Iakovlev testified that he could not identify prior Mersilene mesh specimens that he had reviewed prior to Wave 8:

Q. How many Mersilene specimens have you reviewed in your practice?

A. I had several of explanted multifilament polyester meshes because most of them came through, or I think all of them came through -- all except this one -- came through just regular diagnostic work from surgeons. They were all hernia specimens. **I don't think I ever had Mersilene mesh used for sacropexy.** This is the first case. **How many of those were Mersilene? It's hard to say, because when it's a diagnostic sample, there's no sticker and sometimes you cannot trace what it was.** It is polyester and it is multifilament. I would say less than ten, maybe ten, somewhere in that range.

Q. Okay.

A. But it's just an estimate. I never counted them.

Dep. Tr. 8:20-9:14 (emphasis added). This testimony, along with additional testimony that Dr. Iakovlev has not focused on Mersilene mesh or multifilament mesh in his prior research or work, was detailed in Ethicon's memorandum at 3-4. The Plaintiff conflates Mersilene mesh and multifilament polyester mesh. *See* Pl. Resp. at 2-3. This conflation, found in both the Plaintiff's response and in Dr. Iakovlev's testimony and opinions, highlights that Dr. Iakovlev has an insufficient basis for his opinions. Because Dr. Iakovlev cannot confirm whether he has previously seen a Mersilene mesh, he reverts to comparing the mesh to all multifilament polyester meshes. Because Dr. Iakovlev's opinions lack sufficient basis with respect to Mersilene mesh, notably on specifics for risk of erosion and infection, he retreats to data gathered from other devices.

Dr. Iakovlev did not undertake the analysis necessary, through his own research or that of others, to determine how Mersilene mesh specifically compares to these other meshes (whether monofilament, multifilament, polypropylene, and/or polyester). Instead, Dr. Iakovlev seeks to testify that Mersilene mesh, as a multifilament polyester mesh, has a higher risk of erosion and

infection compared to other designs, even though Dr. Iakovlev did not determine the overall rate of these complications with Mersilene mesh. *See* Dep. Tr. 25:25-26:6.²

As here, Dr. Iakovlev has in other litigation previously attempted to buttress his limited experience with a certain mesh by relying on mesh of differing designs. In the ObTape litigation, as discussed in Ethicon's memorandum, Dr. Iakovlev's opinions were excluded by two courts. The Plaintiff attempts to distinguish those two cases, where Dr. Iakovlev sought to offer similar opinions as those here. The Plaintiff incorrectly contends that the *Young* and *Clinton* cases involved only Dr. Iakovlev's degradation opinions. *See* Pl Resp. at 6-7.³

The Plaintiff is correct that "Young also involved opinions regarding polypropylene degradation . . . opinions that are not at issue in this case." Pl. Resp. at 7 (citation omitted). Plaintiff fails to acknowledge the Court in *Young* also excluded Dr. Iakovlev's opinions regarding both erosion and infection with ObTape (unrelated to degradation):

As for ObTape 'specifics,' Dr. Iakovlev states that in the course of his research and involvement in litigation, he has examined specimens in 10 ObTape cases. He states, 'In cases where an adequate history was provided[,] the complications included mesh erosion in all cases (100%). This was different from other sling types which had erosions listed as a complication in 30–40% of mesh explants.' Dr. Iakovlev does not provide the number of ObTape cases that included an 'adequate history.' Finally, Dr. Iakovlev concludes that the cumulative effects of ObTape design features result in 'higher mucosal erosion rates' and 'persistent infection that cannot be cleared by the body and can spread through the deep tissues.'

Young v. Mentor Worldwide LLC, 312 F. Supp. 3d 765, 771 (E.D. Ark. 2018). As such, the Plaintiff is incorrect on the scope of the opinions addressed in *Young*. In this case, Dr. Iakovlev has engaged less of an analysis of Mersilene specimens than he did with ObTape, where his

² As discussed later, Dr. Iakovlev also did not know whether Mersilene mesh implanted for abdominal sacrocolpopexy had a higher or lower risk of erosion and infection compared to ObTape. *See* Tr. 99:8-21. This was despite the fact he seeks to offer opinions regarding ObTape in this litigation involving Mersilene.

³ In *Clinton*, Dr. Iakovlev's general causation opinions regarding degradation were excluded. The Court then excluded his specific causation opinions, including infection, because his general causation opinions failed to pass Daubert scrutiny.

opinions were excluded. Moreover, as the Court found in *Young*, opinions regarding meshes with different designs and compositions are not helpful:

The Court finds that neither Dr. Iakovlev's explanation nor the Youngs' arguments demonstrate that information about various types of polypropylene mesh products (which according to Dr. Iakovlev, cause different types of pathological changes depending on the product) is relevant in this case, which deals with a specific mesh product, used for a specific purpose.

Young, 312 F. Supp. 3d at 771. Here Dr. Iakovlev seeks to testify regarding meshes of different constructions and materials.⁴ Dr. Iakovlev's opinions in this case fail for the same reasons as the Court found in *Young*.

Further, the Plaintiff correctly asserts that Dr. Iakovlev is not offering the opinion that polyester degrades in vivo. *See* Pl. Resp. at 7. In fact, Dr. Iakovlev opines in his case specific report for Ms. Berden (which he completed before his "general" report on Mersilene mesh) that:

The mesh fibers showed no surface degradation which was in keeping with a material other than polypropylene. This was also in keeping with Mersilene mesh, as it is made of polyester.

Case Specific Report of Vladimir Iakovlev, Cheryl Berden, dated June 4, 2018, at 26. The ObTape device at issue in *Young* and *Clinton* is composed of polypropylene, which Dr. Iakovlev contends degrades in the body. In his excluded opinions in *Young* and *Clinton*, he attempted to link degradation to clinical complications. In the Ethicon litigation involving Mersilene mesh, Dr. Iakovlev seeks to paint Mersilene with his ObTape brush without an adequate explanation of how the differences in the two products (e.g., lack of degradation) impact the rates of clinical complications he seeks to testify about – erosion and infection.

⁴ The Plaintiff's response notes "[b]y contrast, Dr. Iakovlev's opinion [sic] are specific to Mersilene, specific to multifilament mesh, and specific to this case, Ex. B. at 3-12, as even Defendants concede. Pl. Resp. at 7 (citing – incorrectly – footnote 2 on page 3 of Ethicon's memorandum). It is unclear which footnote the plaintiff intends to cite because Ethicon's page 3 contains footnote 1, while page 4 contains footnote 2. In any event, the opinions found in Dr. Iakovlev's supplemental report on Mersilene mesh apply to Ms. Berden's case but they are general opinions that are not specific to Ms. Berden. Moreover, as the remainder of the Plaintiff's response makes clear, Dr. Iakovlev's opinions are hardly specific to Mersilene or to multifilament mesh.

Plaintiff's attempts to distinguish Dr. Iakovlev's excluded ObTape from his Mersilene opinions undercut the entire basis for his opinion. He cannot argue in one case that the differences in mesh construction are important and argue in this case that the differences in construction are irrelevant. *See* Pl. Resp. at 7.⁵ His effort to do so shows that, rather than following a scientific method, Dr. Iakovlev changes his opinions as a given litigation suits him.

Dr. Iakovlev's opinions are unreliable, lack a sufficient basis, and are unhelpful.

As detailed in Ethicon's memorandum, Dr. Iakovlev's opinions regarding erosion and infection risk with Mersilene mesh are unreliable and not supported by a sufficient basis. Moreover, his opinions based on review of non-Mersilene meshes are unreliable and unhelpful. Thus, Dr. Iakovlev's opinions should be excluded.

At its core, the Plaintiff's response is that Dr. Iakovlev's opinions are largely supported by the classification of Mersilene mesh as an Amid⁶ Type III mesh due to its multifilament construction and, as a result, are associated with higher risks of erosion and infection. *See, e.g.*, Pl. Resp. at 4 (Dr. Iakovlev's "opinions focus on differences in infection and erosions [sic] rates

⁵ After several pages attempting to explain that Dr. Iakovlev could opine about other meshes (wherein his admitted focus was polypropylene), the Plaintiff inexplicably attempts to distinguish the *Young* case by stating:

In contrast to this case, the *Young* opinions 'cover[ed] all types of polypropylene mesh products,' and Dr. Iakovlev testified that 'complications from polypropylene mesh products are somewhat different depending on the device implanted.' *Id.* Based on this testimony, the *Young* court concluded that ObTape-specific data was necessary. *Id.* As in *Clinton*, the court found significant that Dr. Iakovlev's general opinions were, unlike here, were formulated from work in other litigations and not specific to ObTape.

Pl. Resp. at 7.

⁶ Further showing that Dr. Iakovlev fails to adhere to a consistent methodology, in other litigations he has chosen to dispute the Amid classification. In fact, he does not discuss it with respect to meshes composed of Prolene or Prolene Soft. *See* Expert Report of Dr. Vladimir Iakovlev (Wave 1 General Report), dated 11/9/2017. This is because doing so in that context would require Dr. Iakovlev to admit that Prolene and Prolene Soft meshes are considered macroporous, Type I meshes as defined in Amid, which would not be helpful to his opinions in those cases.

by design—monofilament versus multifilament...”); *id.* at 9 (Dr. Iakovlev testified that “overall, class 3 meshes have higher risks of infection than class 1.”)

Dr. Iakovlev is seeking to not merely testify that Amid Type III meshes have a higher risk of infection, but to bolster his opinions regarding Mersilene mesh by stating it must have a higher rate of infection because it is Amid Type III. He cannot do so because he has not done the work or analysis that would reliably permit the conclusion: conducting or relying upon studies that show the risk specific to the device in question. *See* Def. Memo at 4-13.

Plaintiff’s Daubert response highlights Dr. Iakovlev’s reliance on the 1997 mesh classification system described by P.K. Amid. *See, e.g.*, Pl. Resp. at 4-5, 12-13. Dr. Iakovlev bases his opinion that Mersilene mesh has a higher rate of infection on it being classified as an Amid Type III mesh. *See* Iakovlev Report at 4-6, 11. The Plaintiff points to the importance of the Amid classification in her Response. *See, e.g.*, Pl. Resp. at 4-5. This reliance is misplaced as the Amid publication forming the basis of the classification—and cited by Dr. Iakovlev—concluded that “[t]he risk of infection can be avoided by utilization of **Type III** and particularly Type I prostheses.” *See* Amid PK. *Classification of biomaterials and their related complications in abdominal wall hernia surgery*. Hernia; 1997: 1:15-21, at 20 (emphasis added) (noting Mersilene as Type III). Moreover, Dr. Iakovlev has not supported his opinions specific to Mersilene mesh with data showing increased risk of infection or erosion as compared to other meshes. Instead, he did not undertake an effort to learn the overall rate of these complications with Mersilene Mesh. *See* Dep. Tr. 23:17-24:8. As a result, he has accepted the Amid classification but has not undertaken an analysis to determine whether it is correct with respect to Mersilene mesh.⁷

⁷ As discussed later, he has done the same when considering ObTape alongside Mersilene mesh.

To the extent the Plaintiff argues the Amid classifications support Dr. Iakovlev's opinion regarding erosion, this is contradicted by Dr. Iakovlev himself. As Plaintiff notes, the Amid classification system was developed in relation to hernia mesh. Pl. Resp. at 5. Dr. Iakovlev opined that erosion is not typically seen with hernia mesh. Dep. Tr. 28:21 (hernia mesh rarely erodes). Thus, Plaintiff's argument that Amid provides a basis for Dr. Iakovlev's opinion that Mersilene mesh carries a higher rate of erosion is contradictory to his opinion and, thus, does not provide a basis for his opinion.

Without the Amid classification to provide support for his opinion, the only support Dr. Iakovlev cites specifically relevant to the risk of erosion with Mersilene mesh is the Visco article where Dr. Iakovlev disagreed with the reported erosion rate. See Def. Memo. at 11-12. The Plaintiff asserts Dr. Iakovlev simply testified that the study "underestimated complication rates." Pl. Resp. at 10-11. This interpretation glosses over Dr. Iakovlev's report and testimony where he opined that the actual rate should be double or triple the reported rate. See, e.g., Iakovlev Report at 8-10. Neither Dr. Iakovlev nor the Plaintiff can provide any principled basis to ignore the published rate in favor of a different rate. Without it, Dr. Iakovlev has no basis for his opinions regarding the risk of erosion with Mersilene mesh. As a result, these opinions should be excluded. See *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *38 (S.D. W. Va. April 28, 2016) (finding that citation to merely one article in support of opinion was insufficient).

Mistaking the mesh matters

As stated in Ethicon's memorandum, one deficiency in Dr. Iakovlev's opinions is his mistaken reliance on a Marlex study. See Def. Memo. at 10-11. The Plaintiff downplays this mistake, but this is unavailing. The plaintiff incorrectly states: "Defendants point to testimony where Dr. Iakovlev mentions a study evaluating Marlex and a Mersilene study." Pl. Resp. at 10.

Contrary to the Plaintiff's assertion, the single study in question did NOT evaluate Mersilene, which is precisely why Dr. Iakovlev's reliance on it in his report for his Mersilene mesh opinions is important. Dr. Iakovlev's reliance on a study involving a monofilament polypropylene mesh – Marlex – was no “slip of the tongue” as the Plaintiff suggests. Dr. Iakovlev not only cited in his report this paper he mistook for Mersilene, he quoted from it in his report in a section devoted to specifics of Mersilene, and opined at his deposition that it provided an example that the Mersilene mesh design can result in the relevant complications. Dep. Tr. 43:5-22, 43:23-44:9. Instead of supporting his opinions, this Marlex study showed that the monofilament polypropylene Marlex mesh (an Amid Type I mesh) also carries a risk of infection, and his failure to determine the overall rate of complications with Mersilene mesh render his opinions unreliable.

Implantation location is important to Dr. Iakovlev (except when it does not suit him)

The Plaintiff contends Ethicon's argument is misplaced regarding the failure of Dr. Iakovlev to square his inconsistent opinions about the importance of implantation location (i.e., reliance on hernia mesh literature while also holding an opinion that the pelvic floor is a “critical anatomic location”). See Pl. Resp. at 5. Plaintiff points to the Mersilene mesh Instructions for Use (“IFU”), wherein hernia surgery is contemplated. The Plaintiff's assertions regarding the Mersilene mesh IFU miss the mark with respect to whether Dr. Iakovlev's opinions are properly supported by general hernia mesh literature (non-specific to Mersilene mesh). It is Dr. Iakovlev's own opinions that emphasize the location in which mesh is implanted – here, in the female pelvic floor – and on the importance of mesh design. See Def. Memo. at 5-6. Dr. Iakovlev's failure to follow his own prior opinion shows that he does not follow the scientific

method. Rather, he changes his methodology to reach the opinion that best suits his client's position in each particular case. This clearly demonstrates that his opinions are unreliable.

The Court should exclude Dr. Iakovlev's opinions regarding ObTape.

Dr. Iakovlev cannot inject the complication rates from the ObTape device into the Mersilene mesh litigation. His attempts to do so are unreliable. The context of the broader litigation should not be lost as it illustrates the unreliability of Dr. Iakovlev's opinions. If Plaintiff's response is taken literally, Dr. Iakovlev must not be offering the opinion in cases involving meshes composed of Prolene or Prolene Soft that those monofilament polypropylene meshes cause erosion or infection:

But it is the multifilament design that makes ObTape so relevant to Dr. Iakovlev's opinions. The 'main issue with multifilament meshes,' explains Dr. Iakovlev, is mesh exposure and infection. Ex. A at 12:23-13:2. It is the multifilament design, whether the filaments are made of polyester, as with Mersilene, or polypropylene, as with ObTape, that **'introduces additional risks, and the risks are erosion and especially infection.'** Ex. A at 13:7-13, 67:11-13, 96:13-17. That's why Mersilene's 'main feature is multifilament; polyester is secondary.' Ex. A at 66:21-67:13.

Pl. Resp. at 11 (emphasis added). But this is not the case; as the Court is well aware, Dr. Iakovlev is also offering erosion and infection opinions in the broader litigation involving meshes composed of Prolene or Prolene Soft. Here, Dr. Iakovlev cannot offer the opinion that Mersilene mesh carries a different risk of erosion or infection than ObTape. In fact, he does not offer a rate of either complication with Mersilene despite his attempts to opine that it is higher than other meshes.

Dr. Iakovlev testified that he does not know whether ObTape and Mersilene mesh carry similar risks of erosion and/or infection. He did not focus his work on specific complication rates; instead, Dr. Iakovlev relies on how a device was classified in the Amid system to determine whether it carries a greater risk of infection. *See* Tr. 24:13-25:6, 25:25-26:6. As a

result, he cannot reliably offer opinions comparing the complications experienced with the two products, and he should not be permitted to draw any parallels between the products without this information – or, as the Plaintiff puts it, that “ObTape’s performance substantiates Dr. Iakovlev’s opinions about Mersilene”, *see* Pl. Resp. at 13.

The Court should exclude Dr. Iakovlev’s opinions regarding an internet search he performed because those opinions are unreliable and Dr. Iakovlev is not qualified to provide them.

Perhaps recognizing Dr. Iakovlev’s opinion is flawed, the Plaintiff downplays the emphasis Dr. Iakovlev places on the use of data from a website purporting to provide a search of PubMed articles. *See* Pl. Resp. at 13-17. The plaintiff repeats that Dr. Iakovlev draws no conclusions from the graph, but merely uses it as “one of the indicators” for identifying interest in Mersilene mesh. *See* Pl. Resp. at 14-16. Whether used as a conclusion or an indicator for some other conclusion, any reliance on the data and opinions drawn from it should be excluded. As stated in Ethicon’s memorandum, Dr. Iakovlev’s methodology is flawed, his opinion is unreliable, and he is not qualified to opine on what are essentially “market trends”. *See* Def. Memo. at 14-15.

CONCLUSION

For the foregoing reasons and those set forth in Defendants' initial briefing, Defendants respectfully request that the Court exclude Dr. Iakovlev's testimony in these cases.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on November 1, 2018, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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